IN THE INTERNATIONAL BUREAU OF WIPO

ELI LILLY AND COMPANY, et al.) Authorized Officer:) Catherine Humbert
International Application))
Number PCT/US00/16140	Mailing Date 24 January 2001
International Filing Date)
12 June 2000	Agent's File Reference:
Title of Invention	7040339LLY54
PHARMACEUTICAL MATERIALS AND)
METHODS FOR THEIR PREPARATION AND USE)

RESPONSE TO THE INTERNATIONAL SEARCH REPORT

The International Bureau **WIPO** 34, chemin des Colombettes 1211 Geneva 20 Switzerland

Dear Sir/Madam:

In response to the International Search Report mailed 13 December 2000, regarding the above-referenced PCT Patent Application, Applicant does not wish to make any amendments at this time.

Respectfully submitted

Thomas Q. HENRY, #28,509

Woodard, Emhardt, Naughton,

Moriarty & McNett

Bank One Center/Tower, Suite 3700

111 Monument Circle

Indianapolis, Indiana 46204 US

United States of America

(317) 634-3456

C 10/018043

JC07 Rec'd PCT/PTO 1 0 DEC 2001

IN THE EUROPEAN PATENT OFFICE

In re PCT application of ELI LILLY AND COMPANY,) Authorized Officer:) M Uhl
et al.). }
International Application)
Number PCT/US00/16140) Mailing Date
) 25 July 2001
International Filing Date)
12 June 2000) Agent's File
) Reference:
Title of Invention) 7040339LLY54
PHARMACEUTICAL MATERIALS AND)
METHODS FOR THEIR PREPARATION	
AND USE	í

RESPONSE TO WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

The International Preliminary Examining Authority European Patent Office Erhardstrasse 27 D-80298 Munich Germany

Dear Sir:

In response to the Written Opinion from the International Preliminary Examining Authority mailed 01 June 2001, Applicant does not wish to make any amendments.

Respectfully submitted

Thomas Q. HENRY, #28,309

Woodard, Emhardt, Naughton,

Moriarty & McNett

Bank One Center/Tower, Suite 3700

111 Monument Circle

Indianapolis, Indiana 46204 US

United States of America

(317) 634-3456

	DATE. 12 June 2000
PCT INTERNATIONAL APPLICATION TRANSMITTAL LETTER REGARDING THE INTERNATIONAL APPLICATION OF	DOCKET OR REFERENCE NUMBER
ELI LILLY AND COMPANY, et al.	7040339LLY54
ENTITLED PHARMACEUTICAL MATERIALS AND METHODS FOR THEIR P	REPARATION AND USE
Certification under 37 CFR 1.10 (if	applicable) 12 June 2000
EL016471679US	Date of Deposit
"Express Mail" mailing number	
I hereby certify that this application is being deposited with the United Sta Addressee" service under 37 CFR 1.10 on the date indicated above and is Trademarks, Washington, D.C. 20231.	
LINUA S.W. CONRAG	Ada S. W. Conral
(Typed or printed name of person mailing application)	(Signature of person mailing application)
To the United States Receiving Office (RO/US): Accompanying this transmittal letter is the above-identified Inter Request form (PCT/RO/101). Please process the application accordation Treaty.	national application, including a completed ling to the provisions of the Patent Cooper-
The following requests are made of the RO/US: 1. PREPARATION AND TRANSMITTAL OF CERTIFIED Concepts and transmit to the International Bureau a certification documents identified in Box VI of the Request form (37 CFR)	1.451).
To cover the cost of copy preparation and certification (37 CF KX) a (check) (money order) in the amount of \$\frac{15.00 inc}{2}\$	cluded is attached to this transmittal letter.
The BOJ'S is berely authorized to charge the following de	posit account no.:
2. XX CHOICE OF INTERNATIONAL SEARCHING AUTHOR Search be performed by the following International Searching	RITY—It is requested that the international
United States Patent and Trademark Office (ISA/US)	
European Patent Office (ISA/EP)	Colculation Sheet
The appropriate Search fee for the above-named Authori (PCT/RO/101 Annex).	
3. SUPPLEMENTAL SEARCH FEES (ONLY WHEN ISA SEARCH.)—Please charge any Supplemental Search fees International Searching Authority (ISA/US) to deposit account	unt no.:
I pulsestante that the continuent of an exception of a significant conferentiate the real in our contacts against the amount of the Supplemental Sogration for some or secrets an adminis-	is instance and that it in no discount for some timely complete tenture aid to assure that the ISA/US have timely complete.
NOTE: SUPPLEMENTAL SEARCH FEES FOR ISA/EP ARE P	
4. XX DISCLOSURE INFORMATION—In order to assist in so cation for purposes of determining whether a license for for and for other purposes, the following information is supplied	i. *
A. There is no prior filed application relating to this in	vention.
A. There is no prior filed application relating to this in B. There is a prior application, serial number 60/1 which contains subject matter that is	
1. substantially identical to that of the accompanying Into	ernational application. The additional seep
matter of the International application appears. 3. more than that of the accompanying International	national application.
C. Disclosure information cannot be covered by the involvement of several prior applications or	language of Points 4A or 4B above due to the for other reasons. A separate sheet on ttached to this transmittal letter.
5. XX REQUEST FOR FOREIGN TRANSMITTAL LICENS 184 and 37 CFR 5.11, a license to transmit the accompany or international authorities is hereby requested.	no it and to the provisions of on Civici
SIGNER IS THE	
Thomas Q. H	HENRY
COMMICH PEPPESENTATIVE	
Matriane a acenti #29 309	dad XXX

Sheet No. . 2. .

Agent's Ref: 7040339LLY54

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)				
If none of the following sub-boxes is used, th	is sheet should not be in	icluded in the request.		
Name and address: (Family name followed by given name; for a designation. The address must include postal code and name of count address indicated in this Box is the applicant's State (that is, country, of residence is indicated below.) CHMIELEWSKI, Jean A. 511 South 9th Street Lafayette, Indiana 47901 US	This person is: applicant only applicant and inventor inventor only (If this check-box is marked, do not fill in below.)			
State (that is, country) of nationality: US	State (that is, country) of	residence: US		
This person is applicant all designated all designated for the purposes of:		United States America only the States indicated in the Supplemental Box		
Name and address: (Family name followed by given name; for a ladesignation. The address must include postal code and name of cour address indicated in this Box is the applicant's State (that is, country, of residence is indicated below.) KAHR, Bart E. 4612 47th Avenue South Seattle, Washington 98118 US	egal entity, full official nby. The country of the of residence if no State	This person is: applicant only applicant and inventor inventor only (If this check-box is marked, do not fill in below.)		
State (that is, country) of nationality: US	State (that is, country) of	residence: US		
This person is applicant for the purposes of: X all designated the United Sta		United States the States indicated in the Supplemental Box		
Name and address: (Family name followed by given name; for a ladesignation. The address must include postal code and name of cour address indicated in this Box is the applicant's State (that is, country) of residence is indicated below.)	egal entity, full official stry. The country of the of the of residence if no State	This person is: applicant only applicant and inventor inventor only (If this check-box is marked, do not fill in below.)		
State (that is, country) of nationality: State (that is, country) of		residence:		
		United States America only the States indicated in the Supplemental Box		
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) This person is: applicant only applicant and inventor inventor only (If this check-box is marked, do not fill in below.)				
State (that is, country) of nationality: State (that is, country) of residence:				
This person is applicant all designated lall designated States except for the purposes of: all designated lall designated States except of America only the States indicated in the Supplemental Box				
Further applicants and/or (further) inventors are indicated on another continuation sheet.				

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BOX I	0.V DESIGNATION OF STATES		
1	llowing designations are hereby made under Rule 4.9(a)	mark the a	pplicable check-boxes; at least one must be marked):
Regional Patent AP ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare			
⊠ E	Protocol and of the PCT MZ MO TAN PAQUE Eurasian Patent: AM Armenia, AZ Azerbaijan, BY I RU Russian Federation, TJ Tajikistan, TM Turkmenistan Convention and of the PCT	Belarus, I n, and any	KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, other State which is a Contracting State of the Eurasian Patent
⊠ EI	DK Denmark, ES Spain, FI Finland, FR France, GB I	Jnited Ki	witzerland and Liechtenstein, CY Cyprus, DE Germany, ngdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, other State which is a Contracting State of the European Patent
⊠ 0 <i>A</i>	OAPI Patent: BF Burkina Faso, BJ Benin, CF Cent GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, other State which is a member State of OAPI and a Contr	MR Mau acting Sta	in Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, iritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any te of the PCT (if other kind of protection or treatment desired,
Natio	nal Patent (if other kind of protection or treatment desired, spe	ecifu on do	ttad linar
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i —	Belarus		Mongolia
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	Denmark	⊠ RU	
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	Vegelshaten	become	boxes reserved for designating States which have party to the PCT after issuance of this sheet:
	Kazakhstan		Nicomin
	Saint Lucia		Antigua & Barbuda
⊠ LK	Sri Lanka	ID MO	Mozambi one
Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. Confirmation for the time limit.			
at the expiration of that time limit. (Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)			



Agent's Ref: 7040339LLY54

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Supplemental Box If the Supplemental Box is not used, this sheet should not be included in the request.

1. If, in any of the Boxes, the space is insufficient to furnish all the information: in such case, write "Continuation of Box No. ..." [indicate the number of the Box] and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient, in particular:

- (i) if more than two persons are involved as applicants and/or inventors and no "continuation sheet" is available: in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below;
- (ii) if, in Box No. II or in any of the sub-boxes of Box No. III, the indication "the States indicated in the Supplemental Box" is checked: in such case, write "Continuation of Box No. II" or "Continuation of Box No. II or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is applicant;
- (iii) if, in Box No. II or in any of the sub-boxes of Box No. III, the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America in such case, write "Continuation of Box No. II" or "Continuation of Box No. II" and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is inventor;
- (iv) if, in addition to the agent(s) indicated in Box No. IV, there are further agents: in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;
- (v) if, in Box No. V, the name of any State (or OAPI) is accompanied by the indication "patent of addition," or "certificate of addition," or if, in Box No. V, the name of the United States of America is accompanied by an indication "continuation" or "continuation-in-part": in such case, write "Continuation of Box No. V" and the name of each State involved (or OAPI), and after the name of each State (or OAPI), the number of the parent title or parent application and the date of grant of the parent title orfiling of the parent application;
- (vi) if, in Box No. VI, there are more than three earlier applications whose priority is claimed: in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI;
- (vii) if, in Box No. VI, the earlier application is an ARIPO application: in such case, write "Continuation of Box No. VI", specify the number of the item corresponding to that earlier application and indicate at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed.
- 2. If, with regard to the precautionary designation statement contained in Box No. V, the applicant wishes to exclude any State(s) from the scope of that statement: in such case, write "Designation(s) excluded from precautionary designation statement" and indicate the name or two-letter code of each State so excluded.
- 3. If the applicant claims, in respect of any designated Office, the benefits of provisions of the national law concerningnon-prejudicial disclosures or exceptions to lack of novelty: in such case, write "Statement concerning non-prejudicial disclosures or exceptions to lack of novelty" and furnish that statement below.

Continuation to Box No. IV Agent

WOODARD, Harold R.; EMHARDT, C. David; NAUGHTON, Joseph A., Jr.; MORIARTY, John V.; McNETT, John C.; HENRY, Thomas Q.; DURLACHER, James M.; REEVES, Charles R.; WAGNER, Vincent O.; ZLATOS, Steve; BEREVESKOS, Spiro; BAHRET, William F.; BROWNING, Clifford W.; FRISK, R. Randall; LUEDERS, Daniel J.; GANDY, Kenneth A.; THOMAS, Timothy N.; SISSELMAN, Kerry P.; JONES, Kurt N.; ALLIE, John H.; BANTA, Holiday W.; COLE, Troy J.; PAYNTER, L. Scott; LOWES, J. Andrew; MEYER, Charles J.; HARRIS, Darrin Wesley; SCHANTZ, Matthew R.; COY, Gregory B.; HIDAY, Lisa A.; DANILUCK, John V.; BROWN, Christopher A.; BRANNON, C. John; SCHWARTZ, Jason J.; USHER, Arthur J. IV; COLLIER, Douglas A.; MYERS, James B. Jr.; STEVENS, Scott J., and ROWE, James L., all of Woodard, Emhardt, Naughton, Moriarty & McNett, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, Indiana 46204 United States of America

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Sheet No. .5 ... Agent's Ref: 7040339LLY54

Box No. VI PRIORITY	CLAIM	□ g.,	ethan mainaita aluim and in dian	11.4.6.1	
Filing date	Number		Further priority claims are indicated in the Supplemental Box.		
of earlier application (day/month/year)	of earlier applicat	national applie			
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11 June 1999	60/138,912	US			
item (2)					
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of the earlier application purposes of the present in	(s) (only if the earlier in international application	application was filed was siled was the receiving Office	,	1)	
* Where the earlier application is Convention for the Protection of	s an ARIPO application, i Industrial Property for wh	t is mandatory to indicate ich that earlier applicatio	in the Supplemental Box at least on was filed (Rule 4.10(b)(ii)). See S	ne country party to the Paris	
	ONAL SEARCHING		7 (
Choice of International Sear (if two or more International S.	ching Authority (ISA)	Request to use resul	ts of earlier search; reference	to that search (if an earlier	
competent to carry out the inter the Authority chosen; the two-lette	national search indicate	Date (day/month/year)	out by or requested from the Internation Number	_	
ISA / EP	. couc may be used).	11 June 1999		Country (or regional Office) 0/138,912 US	
Box No. VIII CHECK LIS	T. LANGUAGE OF	FUINC			
This international application			companied by the item(s) mark		
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request :	5	rate signed power of at	tornev		
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Figure of the drawings which should accompany the abstract: Language of filing of the international application: English					
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Applicant(s):	ame of the person signing an		person signs (if such capacity isnot obvi	ous from reading the request).	
ELI LILLY AND COMPA	ŊY	Agen	t: //		
ELI LILLY AND COMPANY LEWIS, Jerry CHMIELEWSKI, Jean A. KAHR, Bart E.					
CHMIELEWSKI, Jean A.					
KAHR, Bart E.					
(Thomas Q. Henry)					
1 Deteroferent in Cal	F	or receiving Office use	only —		
Date of actual receipt of the international application:				2. Drawings:	
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:					
4. Date of timely receipt of the required corrections under PCT Article 11(2):					
5. International Searching Aut (if two or more are compete	thority ent): ISA /		ansmittal of search copy delayed til search fee is paid.	i	
For International Bureau use only					
Date of receipt of the record co by the International Bureau:					

- For receiving Office use only -PCT International Application No. REQUEST International Filing Date The undersigned requests that the present international application be processed Name of receiving Office and "PCT International Application" according to the Patent Cooperation Treaty. Applicant's or agent's file reference (if desired) (12 characters maximum) 7040339LLY54 Box No. I TITLE OF INVENTION PHARMACEUTICAL MATERIALS AND METHODS FOR THEIR PREPARATION AND USE Box No. II **APPLICANT** Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence is indicated below. This person is also inventor. of residence is indicated below.) Telephone No. ELI LILLY AND COMPANY Lilly Corporate Center Facsimile No. Indianapolis, Indiana 46285 US Teleprinter No. State (that is, country) of nationality: State (that is, country) of residence: US US the States indicated in the Supplemental Box This person is applicant all designated States X all designated States except the United States of America the United States for the purposes of: of America only Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S) Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State This person is: of residence is indicated below.) applicant only LEWIS, Jerry 14104 Old Mill Circle applicant and inventor Carmel, Indiana 46032 US inventor only (If this check-box is marked, do not fill in below.) State (that is, country) of nationality: State (that is, country) of residence: US US This person is applicant all designated States all designated States except the United States of America the United States of America only the States indicated in the Supplemental Box X for the purposes of: Further applicants and/or (further) inventors are indicated on a continuation sheet. Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE The person identified below is hereby/has been appointed to act on behalf common representative X agent of the applicant(s) before the competent International Authorities as: Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) Telephone No. HENRY, Thomas Q. 317-634-3456 WOODARD, EMHARDT, NAUGHTON, MORIARTY & MCNETT

Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the

space above is used instead to indicate a special address to which correspondence should be sent.

Form PCT/RO/101 (first sheet) (July 1998; reprint July 1999)

SEE CONTINUATION TO BOX NO. IV ON SHEET NO. 4

Bank One Center/Tower, Suite 3700

Indianapolis, Indiana 46204 US

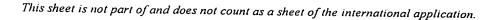
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See Notes to the request form

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317-637-7561



PCT For receiving Office use only FEE CALCULATION SHEET International application No. Annex to the Request Applicant's or agent's file reference 7040339LLY54 Date stamp of the receiving Office Applicant ELI LILLY AND COMPANY, et al. CALCULATION OF PRESCRIBED FEES 1. TRANSMITTAL FEE . 240 T SEARCH FEE S 990 International search to be carried out by (If two or more International Searching Authorities are competent in relation to the international application, indicate the name of the Authority which is chosen to carry out the international search.) 3. INTERNATIONAL FEE Basic Fee The international application contains 81 427 510 remaining sheets additional amount Add amounts entered at b1 and b2 and enter total at B . 937 Designation Fees The international application contains 86 designations. number of designation fees amount of designation fee payable (maximum 10) Add amounts entered at B and Dand enter total at I . (Applicants from certain States are entitled to a reduction of 75% of the international fee. Where the applicant is (or all applicants are) so entitled, the total to be entered at I is 25% of the sum of the amounts entered at B and D.) 4. FEE FOR PRIORITY DOCUMENT (if applicable) 15 Р 5. TOTAL FEES PAYABLE . . 2918 Add amounts entered at T, S, I and P, and enter total in the TOTAL box TOTAL The designation fees are not paid at this time. MODE OF PAYMENT authorization to charge Х bank draft deposit account (see below) coupons Х cheque cash other (specify): postal money order revenue stamps DEPOSIT ACCOUNT AUTHORIZATION (this mode of payment may not be available at all receiving Offices) The RO/ US is hereby authorized to charge the total fees indicated above to my deposit account. (this check-box may be marked only if the conditions for deposit accounts of the receiving Office so permit) is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account. is hereby authorized to charge the fee for preparation and transmittal of the priority document to the International Bureau of WIPO to my deposit account. 23-3030 Lune Deposit Account No. Date (day/month/year) Signature Thomas Q. HENRY #28,309